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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,122	07/20/2007	Fiona Obrock Geiser	JMYT-368US	9855
23122	7590	01/29/2008	EXAMINER	
RATNERPRESTIA			DENTZ, BERNARD I	
P O BOX 980			ART UNIT	PAPER NUMBER
VALLEY FORGE, PA 19482-0980			1625	
			MAIL DATE	DELIVERY MODE
			01/29/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/584,122	Applicant(s) GEISER ET AL.	
	Examiner Bernard Dentz	Art Unit 1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6-23-2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                 | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 and 12 are rejected under 35 USC 101 as being inoperative and therefore as lacking utility. See comparative ex. 1 at p.8 of the specification. It shows that when the mixture is subjected to supercritical chromatography using carbon dioxide over a derivatized polysaccharide that preparative purification of (-)- trans-tetrahydrocannabinol from the DPA-iso impurity was not achieved. It appears that a further chromatographic step using an achiral stationary phase is necessary for separation of the above from its impurities is required.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al or Backstrom et al or Later et al each in view of Levin et al. All of the references were cited by applicants. The first 3 references all disclose the separation and identification of the various cannabinoid compounds with a concentration on separation and identification of delta-9-tetrahydrocannabinol. See particularly the par. bridging p.146 and 147 of Cole, p. 94, col. 1, Fig. 4 and p. 95, col. 2, third complete par. of Backstrom and p. 251, especially Fig. 5 of Later. These all show that chromatography using a mobile phase comprising carbon dioxide over various materials as the stationary phase can separate delta-9- tetrahydrocannabinol from a mixture comprising it and other cannabinoids.

The difference from instant invention of claims 1-7 and 12 is that a derivatized polysaccharide as the stationary phase is not taught.

However Levin discloses the resolution of (-)-delta-9-tetrahydrocannabinol from the corresponding (+) compound and their separation from the corresponding delta-8 isomers using a amylose tris(3,5-dimethylphenylcarbamate) i.e. a derivatized polysaccharide as the stationary phase. See the last line of p. 60 thru the. of p. 61.

Although alcohols are used as the mobile phase it would have been obvious, in view of Levin in view of its teaching of the salutary effects of using the instant derivatized polysaccharide as the stationary phase in cannabinoid chromatographic processes, to use said stationary phase in the process using a mobile phase comprising carbon dioxide taught by the primary references.

The use of a second chromatography purification step using an achiral stationary phase and passing a mobile phase through it as recited in claims 8-11 is obvious for the following reasons. The first 3 references teach purification of cannabinoids using achiral columns and of course it would be obvious to increase separation and enantiomeric purity by using a step where isomeric and related cannabinoids are separated as taught by the first 3 references and a step using the chiral stationary phase as taught by Levin where enantiomeric cannabinoids are separated.

Applicants faxed in copies of the 4 cited references which are not clear. Applicants are asked to provide clear copies of each of these references.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster et al, US Patent 6,403,126 cited by applicants in view of Levin et al. The rejection is for the same reasons as above. Webster discloses the combination of

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carbon dioxide extraction and column chromatography in the purification of delta-9-tetrahydrocannabinol.

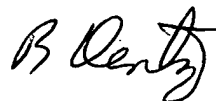
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 571-272-0683. The examiner can normally be reached on Mon-Fri from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dentz

1-24-2008



BERNARD DENTZ  
PRIMARY EXAMINER